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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/605,766	06/28/2000	George W. Hawkins	99,215-A	5882

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EXAMINER

SIEW, JEFFREY

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 03/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/605,766

Applicant(s)

GEORGE HAWKINS

Examiner

Jeffrey Siew

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 December 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,36-60 and 64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1,36-60 and 64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 June 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s). <u>14</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>12,13</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I in Paper No. 11 is acknowledged.

The typographical error involving the duplicate claim 56 has been deleted and replaced by claim

64. The pending claims are ~~36~~³⁶-30 & 64.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a) because they fail to show certain elements as described in the specification e.g. on page 23 line 11 scanner element 36 is not listed in Drawings Figure 10A-10C. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Correction is required. Applicant is advised that all element parts described in specification are listed in appropriate Figures.

Double Patenting

3. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 36-60 & 64 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 33,34,38-47 of copending Application No. 09/464490. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 36-60 & 64 of the instant application are drawn to an apparatus wherein the a volume is enclosed by flexible layer and first substrate surface comprising **at least a first port**. Claims 33,34,38-47 of US09/464490 are drawn to a similar apparatus with **two ports**. Claims 33,34,38-47 of US 09/464490 are drawn to a species of the genus claims of the instant application. The species renders the genus obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claims 1, 36-60 & 64 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6,9 & 10 of copending Application No. 09/492013. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1, 36-60 & 64 of the instant application are drawn to an apparatus wherein the a volume is enclosed by flexible layer and first substrate surface comprising **at least a first port**. Claims 1-6,9 & 10 of copending Application No. 09/492013 are drawn to a similar apparatus with **one port with further limitations of**

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removable cover. Claims 1-6,9 & 10 of copending Application No. 09/492013 are drawn to a species of the genus claims of the instant application. The species renders the genus obvious.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

**THE FOLLOWING IS A NEW GROUND OF REJECTION NECESSITATED BY THE
AMENDMENT**

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 36,37,40,45,47,49 & 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Cottingham et al WO 97/10056 20 March 1997).

Cottingham et al teach an apparatus for performing biological reactions (see whole doc. esp. abstract & figure 4, DNA amplification and probe assay device) comprising a substrate (see page 13 line 3-4 DNA card with bottom and top layer) and an array with biomolecular probes positioned on first surface (see page 10 lines 1-15 teaching an array arrangement of DNA amplification and assay reagents which includes primers and probes spotted on surface) and flexible layer affixed to first surface by an adhesive layer forming reaction volume (see page 13 lines 9 & 10 adhesive binding a plastic film) and port (see page 13 line 21 & last line air vent

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and sample port). The ports extend through flexible layer (see Figure 4 detail 28 & 26). They teach apparatus may further comprise measuring instrument and heated carrier (see figure 13 detail 80, 81 and page 21 first full paragraph).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 43 & 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cottingham et al (WO 97/10056 20 March 1997) over Rehman et al (NAR vol. 27 no. 2 pp. 649-655).

The teachings of Cottingham et al are described previously.

Cottingham do not teach polyacrylamide.

Rehman teach polyacrylamide layer for binding probes (see whole doc. esp. intro).

One of ordinary skill in the art would have been motivated to apply Rehman et al' polyacrylamide to Cottingham et al's device in order to immobilize DNA probes at a greater capacity. Rehman et al state that polyacrylamide provides for great probe capacity, density , lower non-specific binding levels and relatively high thermal stability particularly in amplifications of solid phase PCR and hybridization assays (see intro). It would have been

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prima facie obvious to apply Rehman et al's polyacrylamide to Cottingham device for DNA probe assay in order to increase the hybridization efficiency of the probe reagents.

7. Claims 48,50-56 & 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cottingham et al (WO 97/10056 20 March 1997) over Bjornson et al (WO99/19717 22 April 1999)

The teachings of Cottingham et al are described previously.

Cottingham do not teach flexible layer with polyester, polypropylene.

Bjornson et la teach a variety of well known flexible films such as plastics acrylics and polyethlenes of varying widths.(see whole doc. esp.page 17 line 15-17). They teach rolling with roller (see figure 5). They teach adhesives (see page 25 line 9).

One of ordinary skill in the art would have been motivated to apply Bjornson et al's teachings of rollers and flexible film to Cottingham et al's device in order to construct a cover for the reaction and press to ensure a seal of the film. It would have been prima facie obvious to apply Bjornson et al's teaching of films and roller press in order to ensure a sealed layer in Cottingham et al's device.

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8. Claims 39,41,42, 46, 58, 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cottingham et al (WO 97/10056 20 March 1997) over Bjornson et al (WO99/19717 22 April 1999)

The teachings of Cottingham et al are described previously.

Cottingham do not teach sample chip and heater

Besemer et al teach a chip device containing a substrate having an array of probes attached to cavity (see whole document esp. col. 1 line 65- col.2 line 3 & claim 1 & 2). The body includes two inlets that allow fluids into and through cavity. A seal, plug or any other seal may be provided for each inlet to retain fluid within cavity (see col. 6 line 39). The body is formed by welding two pieces together. They also teach heaters may be connected to device(col. 9 line 62). They also teach of variety of surface supports including glass, silicon , Ge , GaAS (see col. 4 line 60).

One of ordinary skill in the art would have been motivated to insert Besemer et al's chips to Cottingham et al's device in order perform hybridization assays. Array chips were well known and commonly practiced in the art to perform detection assays. It would have been prima facie obvious to apply Besemer et al's chip to Cottingham et al's device in order to perform a plurality of different assays simultaneously.

9. Claim 64 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cottingham et al (WO 97/10056 20 March 1997) in view of Besemer et al (US5,945,337 Aug. 31, 1999) in further view of Van Antwerp et al (US5,786,439 July 28, 1998).

The teachings of Cottingham et al and Besemer et al are described previously.

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Cottingham et al do not teach the the claimed layer of water soluble compound.

Van Antwerp et al teach coating the surface of biosensor with uniform hydrogel (see whole doc. esp. abstract). The hydrogel may be PEG 600(see claim 10).

One of ordinary skill in the art would have been motivated to apply Antwerp PEG-600 coatings to the combined invention of Cottingham et al and Besemer et al's chip array device in order to protect the array from interfering chemicals. Antwerp et al state that the hydrogel layer protects from interfering chemicals such as electrolytes and proteins but allows water to pass through to allow the arrays to accurately measure analyte (see column 1 lines 46-50). It would have been prima facie obvious to apply Antwerp et al's hydrogel to Besemer et al's chip device in order to allow Besemer et al's array to accurately measure analyte without interference from other chemicals.

SUMMARY

10. No claims allowed.

CONCLUSION


11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number is (703) 305-3886 and whose e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m.

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If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Tracey Johnson for Art Unit 1637 whose telephone number is (703)-305-2982.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and Before Final FAX (703) 872-9306 or After Final FAX (703) 30872-9307.


JEFFREY SIEW
PRIMARY EXAMINER

March 3, 2003